



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0083]

Notice of Request for Extension of Approval of an Information Collection; Select Agent Registration

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations for select agent registration.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0083>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0083, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0083> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue

SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for select agent registration, contact Mr. Charles L. Divan, Operations Director, Agriculture Select Agent Services, National Import Export Services, VS, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737; (301) 851-3300, option 3. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

SUPPLEMENTARY INFORMATION:

Title: Select Agent Registration.

OMB Control Number: 0579-0213.

Type of Request: Extension of approval of an information collection.

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) provides for the regulation of certain biological agents and toxins by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS). Under section 212 of the Act, USDA regulates certain biological agents and toxins that have the potential to pose a severe threat to animal and plant health or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within USDA. Select agents and toxins that have been determined to pose a severe threat to both human health and to animal health or animal products are subject to regulation by both APHIS and the Centers for Disease Control and Prevention

(CDC), HHS. CDC has the primary responsibility for implementing the provisions of the Act within HHS.

APHIS regulations for select agents and toxins are contained in 7 CFR part 331 (plant) and 9 CFR part 121 (animal and overlap¹). They require an individual or entity (unless specifically exempted under the regulations) to register with APHIS or with CDC in order to possess, use, or transfer biological agents or toxins.

The registration process is designed to obtain critical information concerning individuals or entities in possession of select agents or toxins, as well as the specific characteristics of the agents or toxins, including name, strain, and genetic information. These data are needed, in part, to allow APHIS to determine the biosafety and biocontainment level of an entity as well as the entity's security situation. This, in turn, helps APHIS to ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the agent or toxin are present at the entity, thus preventing access to such agents and toxins for use in domestic or international terrorism. APHIS will also request information to determine that individuals seeking to register have a lawful purpose to possess, use, or transfer agents or toxins.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

¹ Overlap select agents and toxins are those that have been determined to pose a severe threat to human and animal health or animal products.

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies, such as electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 2.6 hours per response.

Respondents: Researchers, universities, research and development organizations, diagnostic laboratories, and other interested parties who possess, use, or transfer select agents or toxins.

Estimated annual number of respondents: 1,517.

Estimated annual number of responses per respondent: 3.

Estimated annual number of responses: 4,754

Estimated total annual burden on respondents: 12,368 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 4th day of November 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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